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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,246	04/22/2005	Shin Nemoto	123391	1110

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EXAMINER

LARKIN, DANIEL SEAN

ART UNIT PAPER NUMBER

2856

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/532,246

Applicant(s)

NEMOTO, SHIN

Examiner

Daniel S. Larkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>22 April 2005</u> .   | 6) <input type="checkbox"/> Other: ____                           |

**DETAILED ACTION**

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Reference numeral "7", as shown in Figure 1A, does not appear within the written description.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

Reference numeral "12" does not appear within the drawing figures as suggested by the disclosure on page 10, paragraph [0063], line 9.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin

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as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The disclosure is objected to because of the following informalities:

Page 6, paragraph [0041], line 9: The first occurrence of the term "of" should be corrected to read -- for --.

Page 7, paragraph [0046], line 2: The second occurrence of the term "of" should be deleted.

Page 7, paragraph [0046], lines 3 and 4: How are the pulse signals sent to the automatic gain control section, when the frequency bandwidth of the pulses, as described in paragraph [0045], lines 3 and 4, fall outside of the 7-30 Hz range of the band-pass filter?

Page 9, paragraph [0055], line 1: A -- comma -- should be inserted after the term "intensity".

Page 10, paragraph [0063], line 9: Reference numeral "12" should be corrected to read -- 7 --.

Page 10, paragraph [0064], line 1: The abbreviation "FIGs." should be corrected to read -- FIGS. --.

Page 10, paragraph [0065], line 3: The numeral "1" should be corrected to read

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-- one --.

Page 11, paragraph [0066], line 3: The numeral "1" should be corrected to read

-- one --. Appropriate correction is required.

### ***Claim Objections***

6. Claims 16-20 are objected to because of the following informalities:

Re claim 16, claim line 7: The conjunction -- and -- should be inserted after the term "section". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Re claim 5, claim line 9: The phrase "the parameters" lacks antecedent basis.

### ***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to a judicial exception; as such, pursuant to the Interim Guidelines on Patent Eligible Subject Matter (MPEP 2106), the claims must have either physical transformation and /or a useful, concrete and tangible result. The claims fail to include transformation from one physical state to another. Although the claims appear useful and concrete, there does not appear to be a tangible result claimed. Merely, outputting parameters acquired by signal gains to calculate biosignal intensity (claim 1); using the calculated intensity to monitor a bedding state (claim 5); utilizing a bedding state judging means to judge from a plurality of intensity signals or parameters (claim 8); and utilizing a status judgment section based on signal inputs (claim 16) would not appear to be sufficient to constitute a tangible result, since the outcome of the outputting(claim 1)/calculation (claim 5)/judgment (claims 8 and 16) step has not been used in a disclosed practical application nor claimed as made available in such a manner that its usefulness in a disclosed practical application can be realized. As such, the subject matter of the claims is not patent eligible.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-7, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,479,939 (Ogino) in view of JP 2002-052010 (Ohashi et al.).

With respect to the limitations of claims 1-7, Ogino ('939) discloses a sleep detecting apparatus, comprising: a noninvasive sensor (13), which detects biosignals from a lying subject, col. 9, lines 48-52; the signals are amplified (15) and attenuated (14) with respect to other signals, such as noise, col. 9, lines 53-56; the intensity of the output signals are compared to threshold values to calculate biosignal intensity corresponding to a particular body state, col. 9, lines 58-67 through col. 10, lines 1-9. Ogino ('939) further discloses that signals only in the one to ten hertz range are passed through the filter. A timer (8) is disclosed as being used to determine the presence of body motion after a set period of time has elapsed, col. 9, lines 20-37 and col. 10, lines 10-17.

Ogino ('939) fails to disclose using gain control to control the biosignals into a specific range.

Ohashi et al. disclose a sleep condition monitoring device, comprising a noninvasive sensor (2) to measure biosignals from a lying patient. The signals generated by a microphone connected to the sensor undergo gain control (31) prior to the signals being passed through a heartbeat filter (32) and a respiratory filter (33). Modifying the invention of Ogino to provide gain control means would have been obvious to one of ordinary skill in the art as a means of adjusting the level of the signals to a predetermined detection range in order to distinguish the signals from background noises.

With respect to the limitation of claim 17, Ogino ('939) fails to disclose an alarm attached to the status judging means.

Ohashi et al. disclose that an alarm/emergency call can be raised if abnormal , paragraph [0018], lines 3-5 and paragraphs [0030-0035]. Providing alarm means would have been obvious to one of ordinary skill in the art as a means of alerting personal that a patient may be out of bed wandering or that breathing and heartbeat signals may be abnormal and need attention.

12. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,479,939 (Ogino) in view of JP 2002-052010 (Ohashi et al.) and JP 8-131407 (Yamauchi et al.).

With respect to the limitations of claims 8-12, Ogino ('939) discloses a sleep detecting apparatus, comprising: a noninvasive sensor (13), which detects biosignals from a lying subject, col. 9, lines 48-52; the signals are amplified (15) and attenuated (14) with respect to other signals, such as noise, col. 9, lines 53-56; the intensity of the output signals are compared to threshold values to calculate biosignal intensity corresponding to a particular body state, col. 9, lines 58-67 through col. 10, lines 1-9. Ogino ('939) further discloses that signals only in the one to ten hertz range are passed through the filter. A timer (8) is disclosed as being used to determine the presence of body motion after a set period of time has elapsed, col. 9, lines 20-37 and col. 10, lines 10-17.

Ogino ('939) fails to disclose using gain control to control the biosignals into a specific range.



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Ohashi et al. disclose a sleep condition monitoring device, comprising a noninvasive sensor (2) to measure biosignals from a lying patient. The signals generated by a microphone connected to the sensor undergo gain control (31) prior to the signals being passed through a heartbeat filter (32) and a respiratory filter (33). Modifying the invention of Ogino to provide gain control means would have been obvious to one of ordinary skill in the art as a means of adjusting the level of the signals to a predetermined detection range in order to distinguish the signals from background noises.

Ogino ('939) and Ohashi et al. both fail to disclose a second sensor for detecting the absence of a person in bed.

Yamauchi et al. discloses a detector that determines whether or not a person is in a bed, comprising: a bodily action detecting means (2) to detect the bodily actions of a person caused by various factors, such as movement, heartbeat, and respiration; a human body detecting means (3) to determine the presence/absence of a person on the bedding; and a judgment means (13), which judges the state on the bedding corresponding to signals generated by the bodily action detecting means and the human body detecting means. Modifying the invention of Ogino ('939) in view of Ohashi et al. to include a non-bedding detecting sensor, such as one shown in Yamauchi et al., would have been obvious to one of ordinary skill in the art as a means of providing redundancy in order to more accurately determine whether or not a person is on the bedding.

With respect to the limitations of claim 13, Ogino ('939) fails to disclose that the noninvasive sensor is comprised of a capacitive microphone with an attached hollow, elastic tube.

Ohashi et al. disclose that the noninvasive sensor is comprised of a capacitor microphone (20) with an attached hollow tube (4). Replacing the piezoelectric sensor with a microphone and hollow pressure tube would have been obvious to one of ordinary skill in the art because capacitor microphones are very sensitive in detecting minute pressure variations in body movement caused by heartbeats or breathing.

With respect to the limitation of claims 14 and 15, Ogino ('939) disclose that the presence/absence judging means may be operated by an infrared sensor (5) or a weight sensor (39).

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,479,939 (Ogino) in view of JP 2002-052010 (Ohashi et al.) and JP 8-131407 (Yamauchi et al.) as applied to claim 8 above, and further in view of JP 2002-058653 (Nemoto).

Ogino ('939) fails to disclose that the noninvasive sensor comprises a capacitive microphone with a hollow, elastic tube attached, whereby the tube contained a core wire in the center of the tube.

Ohashi et al. disclose that the noninvasive sensor is comprised of a capacitor microphone (20) with an attached hollow tube (4); however Ohashi et al. also fail to disclose a hollow tube having a core wire inserting into the tube.

Nemoto discloses a detecting unit for detecting organismic signals, such as pulse signals, and breath signals, using a pressure detecting tube (13) connected to a capacitor microphone (12, 30). The pressure detecting tube further includes a core wire (23) passing through the center of the tubing. Modifying the tubing of Ohashi et al. with a core wire supported tubing would have been obvious to one ordinary skill in the art as a means of providing a tube having adequate flexibility to detect pressure changes, but enough rigidity such that the tubing does not collapse under the weight of a patient and close off the pressure sensing device.

Replacing the piezoelectric sensor with a microphone and hollow pressure tube would have been obvious to one of ordinary skill in the art because capacitor microphones are very sensitive in detecting minute pressure variation in body movement caused by heartbeats or breathing.

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,479,939 (Ogino) in view of JP 2002-052010 (Ohashi et al.) as applied to claim 16 above, and further in view of JP 8-131407 (Yamauchi et al.).

Ogino ('939) and Ohashi et al. both fail to disclose a second sensor for detecting the absence of a person in bed.

Yamauchi et al. discloses a detector that determines whether or not a person is in a bed, comprising: a bodily action detecting means (2) to detect the bodily actions of a person caused by various factors, such as movement, heartbeat, and respiration; a human body detecting means (3) to determine the presence/absence of a person on the

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bedding; and a judgment means (13), which judges the state on the bedding corresponding to signals generated by the bodily action detecting means and the human body detecting means. Modifying the invention of Ogino ('939) in view of Ohashi et al. to include a non-bedding detecting sensor, such as one shown in Yamauchi et al., would have been obvious to one of ordinary skill in the art as a means of providing redundancy in order to more accurately determine whether or not a person is on the bedding.

15. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,479,939 (Ogino) in view of JP 2002-052010 (Ohashi et al.) as applied to claim 16 above, and further in view of JP 2002-058653 (Nemoto).

With respect to the limitations of claims 19 and 20, Ogino ('939) fails to disclose \ that the pressure detecting element comprises an elongated tube closed at an end and a differential pressure sensor at the other end.

Ohashi et al. disclose that the pressure detecting element comprises an air mat connected to an elongated tube (4) with a differential pressure sensor (20) attached at one end of the tube (4). Providing a differential pressure sensor would have been obvious to one of ordinary skill in the art because differential pressure sensors are very sensitive in detecting minute pressure variation in body movement caused by heartbeats or breathing.

Neither Ogino ('939) nor Ohashi et al. disclose that the pressure detecting element comprising an elongated tube having a closed end, or that the elongated tube is arranged in a serpentine pattern.

Nemoto discloses a detecting unit for detecting organismic signals, such as pulse signals, and breath signals, using a pressure detecting tube (13) arranged in a serpentine pattern at closed at one end. The other end of the tube is connected to a differential pressure sensor (12). Providing a closed tube in a serpentine pattern would have been obvious to one of ordinary skill in the art as a means of expanding the sensing area by providing a sensor that covers a large surface area, but does not disturb the patient because the sensor is very thin and unobtrusive.

### ***Conclusion***


16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Larkin whose telephone number is 571-272-2198. The examiner can normally be reached on 8:00 AM - 5:00 PM Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel Larkin  
AU 2856  
08 March 2007



**DANIEL S. LARKIN**  
**PRIMARY EXAMINER**